CENTER FOR MEDICARE ADVOCACY, INC.

MEDICARE PART D: FORMULARY ISSUES

The Medicare Prescription Drug Coverage: Time to Act
Maine Department of Health and Human Services
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TERMINOLOGY

- Benefit Management Tools. Utilization methods to promote the use of certain drugs over others. Such tools include generic substitution, prior authorization, quantity limits, step therapy or fail first, and tiered cost-sharing.
- Co-payment. Beneficiary's share of cost expressed as a fixed amount.

TERMINOLOGY

- Drug categories. Groupings of drugs reflecting therapeutic uses of drugs based on International Classification of Diseases.
  - Examples: Analgesics, Anticonvulsants, Antidepressants, Cardiovascular, Immunologicals

TERMINOLOGY

- Drug Classes. Subcomponents of categories, based either on chemical structure or on mechanism of action.
  - Examples: Category Analgesic, Classes: opioids and non-opioids; Category Antidepressants, Classes: Monoamine Oxidase Inhibitors, Reuptake Inhibitors
  - Certain classes are further subdivided. Example: Reuptake Inhibitors – SNRI (Seratonin Norepinephrine Reuptake Inhibitor), SSRI (Selective Seratonin Reuptake Inhibitors), Tricyclics

TERMINOLOGY

- Formulary. A list of drugs covered by a particular benefit plan. Based on efficacy, safety and cost-effectiveness
- Formulation substitution and therapeutic equivalency. Substitution of a less expensive therapeutically equivalent drug for a more expensive one.
  - FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) is the guide.
  - Must have identical active ingredients and be expected to have the same clinical effect and safety profile when administered according to label

TERMINOLOGY

- Generic/generic equivalent drugs. A drug the same as a brand name which can be manufactured after the brand's patent has expired. Generics are identical in terms of efficacy, safety, side effects and dosing.
  - Exceptions: Immunosuppressants and drugs with narrow therapeutic index – high rate of side effects – may not be equivalent.

TERMINOLOGY

- Generic substitution. Substituting a generic drug for identical brand-name.
- Prior authorization. A "benefit management tool" requiring the beneficiary to seek approval of coverage in advance of receiving the drug. Generally used in formularies for selected drugs the use of which the benefit manager wants to monitor or discourage, due to, e.g., their toxicity or potential abuse.

TERMINOLOGY

- Step Therapy and "fail first" requirements. Process that begins drug therapy with the most cost-effective and safest drug and progresses to more costly/risky drugs. Beneficiary "progresses" to other drugs only when the first one(s) fail.

TERMINOLOGY

- Tiered formularies. List of prescription drugs in which different drugs have different co-insurance or co-pays. Generic drugs usually belong to the most preferred tier, with the smallest out-of-pocket cost to beneficiary. In Part D, formularies may include a tier with 100% cost-sharing.

WHAT DRUGS ARE COVERED?

- Plans set own formularies:
  - Must include two drugs in each category or class of drugs
    - Plan determines categories and classes
      - Can change them annually, but not more frequently
    - Plan can change individual drugs on formulary with 60 days written notice.

WHAT DRUGS ARE COVERED?

- Plans set own formularies (con't):
  - Not permitted to use formularies to discriminate against expensive classes of beneficiaries
    - Reliance by Plan on United States Pharmacopeia (USP) Model Guidelines provide safe harbor under the anti-discrimination inquiry
    - USP Guidelines for 2006 define 41 therapeutic categories, 32 of which are further divided into classes; overall 146 unique categories or classes. USP will revise guidelines shortly. See www.usp.org/pdf/drugInformation/mmg/finalModelGuidelines2004-12-31.pdf

WHAT DRUGS ARE COVERED?

- CMS Formulary Guidance (http://www.cms.hhs.gov/pdps/FormularyGuidance.pdf)
  - Focus on Three Areas:
    - Pharmacy and Therapeutic (P&T) Committees
    - Formulary lists
    - Benefit Management Tools
  - Guiding principles for review
    - Rely on Existing Best Practices
    - Provide Access to Medically Necessary Drugs
    - Flexibility
    - Administrative Efficiency

WHAT DRUGS ARE COVERED?

- CMS Formulary Guidance (con't)
  - Two drugs in each category and class is "a floor rather than an absolute standard."
  - Safe harbor from using USP Guidelines applies only to categories and classes; CMS will also review drug lists and benefit management tools used by the plan.

WHAT DRUGS ARE COVERED?

- Formularies in 2006 must include all /substantially all drugs in six categories:
  - Anticancer
  - Anticonvulsant
  - Antidepressant
  - Antipsychotic
  - Immunosuppressant
  - HIV/AIDS
- See guidance at http://www.cms.hhs.gov/pdps/formularyqafinalmmrevised.pdf

WHAT DRUGS ARE COVERED?

- Re Six Categories:
  - Only these drugs can be excluded:
    - Iressa
    - Fuzeon (must be listed but may have prior authorization for new users)
    - Either escitalopram or citalopram can be excluded but not both
    - Fosphenytoin
    - Multi-source brands of identical molecular structure
    - Extended release products
    - Not all dosages of required drugs are required

WHAT DRUGS ARE COVERED?

- Re Six Categories:
  - For beneficiaries already stabilized on these drugs when they join the plan, plan cannot use management tools with demonstrating "extraordinary circumstances."
  - For beneficiaries who start using the drugs, other than HIV/AIDS drugs, after joining the plan, management tools may be used.

WHAT DRUGS ARE COVERED?

- Plans can encourage use of certain drugs
  - Tiered co-payments
  - Generic Substitution: Generics to be substituted for brand name drugs
  - Prior authorization: Need plan's approval before get certain formulary drugs
  - Step therapy: Show "preferred drug" doesn't work before getting prescribed drug

TRANSITION PROCESS

- CMS Guidance to Plans
  - To address needs of
    - Beneficiaries stabilized on a drug regimen prior to enrollment
    - Beneficiaries dually eligible for Medicare and Medicaid
  - Transition guidance is suggestive not prescriptive

TRANSITION PROCESS

- CMS Guidance to Plans (con't)
  - Process should address, through P&T committee, procedures for medical review of non-formulary drugs
  - Transition might include temporary "first fill" supply of 30 days of non-formulary drug (90- 180 days for ltc residents with multiple medications)
  - Plans might contact each enrollee prior to effective date to identify individual issues and create solutions.
  - For post-enrollment, unplanned transitions, plans might provide an emergency supply (duration not identified)

TRANSITION PROCESS

- For transition guidance, see
  - http://www.cms.hhs.gov/pdps/transition_process.pdf (March 16, 2005)
- For Long-term care guidance, see
  - http://www.cms.hhs.gov/pdps/LTC_guidance.pdf (March 16, 2005)
- For Emergency Fill for LTC residents, see
  - http://www.cms.hhs.gov/pdps/qafirstfillforltcresidents-final.pdf

EXCEPTIONS PROCESS

- Each drug plan must develop its own Exceptions process
  - To have drug plan cover non-formulary drugs
  - To reduce cost-sharing for formulary drug

EXCEPTIONS PROCESS

- Can request an Exception starting in January 2006
  - *Only Nursing home residents* get drugs during Exception process

IMPLICATIONS OF FORMULARY ON BENEFIT

Formulary Impact on Out of Pocket Costs

- Coverage only available for medications on the plan's formulary
- Out of pocket costs for non-formulary medications will not count towards true out of pocket costs (TrOOP)

INFORMATION ON PART D PLANS

- Formulary Finder
  - The formulary finder allows a user to enter a particular drug regimen to find out which plans in the area have formularies that cover these drugs.
  - www.Plancompare.medicare.gov/formularyfinder/statesselect.asp

INFORMATION ON PART D PLANS

- Drug plan marketing
- *Medicare &You 2006 Handbook*
- Approved plans listed by state: www.cms.hhs.gov/map/map.asp

INFORMATION ON PART D PLANS

- "Compare Medicare Prescription Drug Plans" at www.medicare.gov
  - Information on this tool appears to be unreliable at this time
  - Formulary information on each plan is expected to be available through this tool in early November

RESOURCES

- www.medicareadvocacy.org
  - *Center News*
  - *Healthcare Rights Review*
- www.kff.org
- www.cms.hhs.gov
- www.medicare.gov

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